In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

AMY FAULKENBERRY, on behalf of her minor son, WCF,	*	
Petitioner,	*	No. 19-238V Special Master Christian J. Moran
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Filed: November 1, 2024
Respondent.	*	

M. Clay Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for petitioner; Emily Manoso and Catherine Stolar, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION[1]

WCF suffers from a rare neurologic condition, anti-NMDAR encephalitis. WCF's mother, Amy Faulkenberry, alleges that a hepatitis A vaccine and/or an influenza ("flu") vaccine caused WCF to develop the anti-NMDAR encephalitis. She retained an expert, Lydia Marcus, to support her claim. The Secretary disputes Ms. Faulkenberry's claim that the vaccines injured WCF and has, likewise,

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

supported his position with reports from a neurologist the Secretary retained for this litigation, Eric Lancaster. Following the submission of these reports, the parties advocated through memoranda.

For the reasons explained below, Ms. Faulkenberry is not entitled to compensation. Ms. Faulkenberry has based part of her claim on a level of proof (plausibility) that is lower than the required level of proof, which is preponderant evidence. Under the correct burden of proof, Ms. Faulkenberry has failed to show how either a hepatitis A vaccine or a flu vaccine can cause anti-NMDAR encephalitis. Thus, she is not entitled to compensation.

I. Background[2]

WCF was born in July 2014. Exhibit 11. His early development was typical. WCF saw his primary care provider, Dr. Walker, for respiratory syncytial virus (RSV), bronchiolitis, and an upper respiratory infection (URI) on February 3, February 11, February 16, and February 18, 2015. Exhibit 4 at 3-6. He was reported to be coughing, wheezing, fussy, and congested. Id. Two weeks later, on March 2, WCF was "not sleeping at night," "coughing all night," and had nasal congestion and a fever. Id. at 2.

At WCF's nine-month check up on May 26, 2015, it was noted that ear tubes had been placed three weeks prior. Id. at 175. WCF was diagnosed with bronchiolitis and a URI on September 10, 2015. Id. at 172. WCF returned to Dr. Walker for his 15-month check up on November 2, 2015. Id. at 171. He was reported to have a cough and congestion, and to be fussy and restless at night. Id. Two weeks later, WCF returned with a chief complaint of "cough, congestion, fever, and 'wheezing.'" Id. at 169. Dr. Walker diagnosed WCF with bronchiolitis and wheezing. An RSV test was negative.

[2] Events in WCF's life are presented summarily because this case is being resolved on an element of proof, the causal theory allegedly connecting the hepatitis A and flu vaccines to anti-NMDAR encephalitis, that is largely independent of what happened to him. For more detailed accounts of the medical records, see Pet'r's Br., filed June 6, 2022, at 2-4 and Resp't's Revised Br., filed Feb. 2, 2023, at 2-12.

WCF visited Dr. Walker's office for his 18-month check up on February 17, 2016. Exhibit 4 at 168. During this appointment, WCF received the second dose of the hepatitis A vaccine and flu vaccine. Id.; see also Exhibit 1 at 1.

Four days later, on February 21, 2016, WCF vomited in a Target store. An ambulance arrived and he was taken to a local emergency room. Exhibit 12 at 5-7. In the emergency room, doctors ran various tests and discharged him. Exhibit 9 at 74-88.

The following day, Dr. Walker saw WCF. Dr. Walker diagnosed him with a URI and vomiting. Exhibit 4 at 167.

The next item in the medical records occurred on March 6, 2016. WCF had convulsions. An ambulance again brought him to the hospital. Exhibit 12 at 10. This event marks the *latest* date that WCF might have first manifested symptoms of his anti-NMDAR encephalitis.

Over the next few weeks, WCF saw pediatricians and different neurologists. He was hospitalized for three days. Exhibit 10 at 5-7. Eventually, he tested positive for NMDA antibodies. Id. at 286.

Both experts agree that WCF's diagnosis is anti-NMDAR encephalitis. Exhibit 22 (Dr. Marcus's report) at 2-4; Exhibit A (Dr. Lancaster's report) at 4.

Anti-NMDAR Encephalitis

Anti-NMDAR encephalitis (sometimes referred to as "anti-NMDA receptor encephalitis") is an encephalitis associated with antibodies against the N-methyl-D-aspartate receptors. Dalmau[3]at 63. Typically, the disorder presents as a multistage illness. About 70% of patients present with initial symptoms such as headache, fever, nausea, vomiting, and diarrhea, and progress to psychiatric symptoms within a few days to weeks. Id. at 63-64. In children, the psychiatric symptoms are often difficult to detect, and the first recognized symptoms may be non-psychiatric such as seizures and status epilepticus. Id. at 64. Motor or complex seizures develop in the early stages of anti-NMDAR. Frequency and

[3] Josep Dalmau et al., Clinical experience and laboratory investigations in patients with anti-NMDAR encephalitis, 10 LANCET NEUROL. 63 (2011); filed as Exhibit A-2.

intensity of the seizures generally decreases as the disease progresses, but seizures may resurface at any time. This phase is usually followed by a stage of decreased responsiveness, alternating between agitation and catatonia, and marked by abnormal movements and autonomic instability. Id. Autonomic manifestations frequently include hyperthermia, tachycardia, hypersalivation, hypertension, bradycardia, and hypotension. Id. Patients may become comatose and develop hypoventilation.

About 75% of patients recover or have mild sequelae, with recovery occurring in a multistage process in the reverse order of symptom presentation:

> Patients slowly wake from coma as their autonomic functions stabilize; they are able to follow simple commands and can have appropriate interactions before they recover verbal functions. During this period, patients can become psychotic and agitated again, calming as they recover further . . . Social behavior and executive function symptoms are usually the last to improve, and recovery can be incomplete or delayed by many months.

Id. at 66-67. Patients may be hospitalized for several months, followed by additional months of physical and behavioral rehabilitation. Id. at 67.

After summer 2016, WCF's development generally slowed. See Exhibit 20 at 4-6 (noting that during WCF's well-child visit at five years old, he was assessed as functioning as a three-year-old). Ms. Faulkenberry did not advance any relatively recent medical records as supporting her claim for compensation. See Pet'r's Br. at 4.

II. Procedural History

The procedural history is straightforward, although one wrinkle developed at the end. Represented by Mr. Ragsdale, Ms. Faulkenberry started this case by alleging the flu vaccine and the hepatitis A vaccine caused WCF to develop "acute encephalopathy post immunization and encephalitis/encephalomyelitis following immunization procedure," as well as "severe developmental delay and regression." Pet., filed Feb. 12, 2017, at 2. She periodically submitted medical records and affidavits.

The Secretary opposed the claim for compensation. Resp't's Rep., filed July 31, 2019. The Secretary maintained that although an appropriate diagnosis was unclear, one possibility was anti-NMDAR encephalitis. Id. at 11. (As mentioned

above, diagnosis is no longer an issue because after the Secretary filed his report, both experts agreed with the diagnosis of anti-NMDAR encephalitis.) The Secretary also contended that WCF may have manifested symptoms of anti-NMDAR encephalitis before the vaccination, in particular, that he was fussy and having trouble sleeping by November 2, 2015. Id. at 12. The Secretary also noted that Ms. Faulkenberry had not presented a report from a treating doctor or from a retained expert that causally connected the vaccinations to WCF's condition. Id. at 12.

To facilitate the presentation of reports from experts, a set of instructions were proposed. When the parties did not object, the instructions became final. Order, issued Jan. 27, 2020.

The parties submitted a series of reports from experts. As mentioned, Ms. Faulkenberry retained Dr. Marcus. Dr. Marcus is a board-certified pediatric neurologist. Exhibit 23 (curriculum vitae). Since 2019, she has been an assistant professor of pediatrics at the University of Alabama-Birmingham. At the time of her first report, she had written three articles published in peer-reviewed journals. Id. at 4. Another article reporting on a series of patients with anti-NMDAR encephalitis was pending review. Exhibit 22 at 1. In her first report, Dr. Marcus stated that she has treated approximately nine cases of anti-NMDAR encephalitis. Id.

The Secretary's expert is Dr. Lancaster. Dr. Lancaster is board certified in neurology. Exhibit B (curriculum vitae). He has "expertise in antibody-mediated neurologic disorders." Id. at 1. Dr. Lancaster "completed several years of research fellowship at the University of Pennsylvania under the mentorship of Josep Dalmau, MD, PhD, who discovered anti-NMDAR encephalitis." Exhibit A (report) at 1. Dr. Lancaster has written more than 30 peer-reviewed articles, some of which concern anti-NMDAR encephalitis. Exhibit B at 5-7. At time of his first report, Dr. Lancaster had treated approximately 50 patients with anti-NMDAR encephalitis. Exhibit A at 1-2. The 50 patients appear to be all adults, not children.

Across the series of reports, Dr. Marcus and Dr. Lancaster disputed at least three aspects of the case. First, whether there is a theory by which vaccines can cause anti-NMDAR encephalitis. Second, when WCF first manifested a symptom of his anti-NMDAR encephalitis. Third, whether an infection---and not the vaccines---could have caused the anti-NMDAR encephalitis. See Exhibit 22 (Dr. Marcus's first report, dated Oct. 6, 2020); Exhibit A (Dr. Lancaster's first report,

dated Mar. 22, 2021); Exhibit 44 (Dr. Marcus's second report, dated June 10, 2020); and Exhibit C (Dr. Lancaster's second report, dated Oct. 7, 2021).

Dr. Marcus listed "multiple mechanisms by which autoimmunity in encephalitis can be induced," focusing on molecular mimicry as a "plausible mechanism of vaccination provoking autoimmune encephalitis." Exhibit 22 at 3. "In anti-NMDA receptor encephalitis, auto-antibodies are produced against the cell surface NR1 subunit of the NMDA receptor." Id. Dr. Marcus cited to studies to support the point that there is "some form of molecular homology or mimicry between influenza antigens and the NR1 subunit of the NMDA receptor."[4] Id.

In response, Dr. Lancaster disagreed with Dr. Marcus' theory. He stated that "The key phenomenon which absolutely must occur for anti-NMDAR encephalitis to develop is the creation of specific antibodies targeting a specific 3-dimensional epitope on the GluN1 receptor subunit," and it was "highly unlikely" that a denatured vaccine protein would have a strong resemblance to this structure. Exhibit A at 4. Dr. Lancaster noted several deficiencies in Dr. Marcus's presentation of her theory: Dr. Marcus discussed multiple vaccines but did not specify which would contain the NMDAR mimic; Dr. Marcus did not specify a particular protein as the mimic; Dr. Marcus did not discuss the possibility of an alternative potential trigger such as an infection; and even if a vaccine-induced event was possible, it would not be likely, as "such an event would constitute only a tiny fraction of the thousands of diagnosed cases." Id. at 5.

On the point of potential alternate causes, Dr. Lancaster noted that WCF "had a history of recurrent upper respiratory infections and otitis media throughout childhood." Exhibit A at 5. In particular, he highlighted symptoms of a likely acute gastrointestinal infection on February 21, 2016 and the diagnosis of an upper respiratory infection on February 22, 2016. Additionally, WCF was diagnosed with maxillary sinusitis on March 6, 2016 "when he presented with the first definite symptoms of anti-NMDAR encephalitis." Id. "It is unclear how long this infection had been present/developing prior to this time. There were therefore active infections preceding the onset of the encephalitis." Id. He acknowledged that the night terror-like episodes from February 22 could have been early anti-NMDAR encephalitis symptoms, "but this is not certain." Id.

[4] These are discussed further in the Analysis section of this Decision.

In her supplemental report, Dr. Marcus stated that even if one accepted that WCF had a subclinical infection or if the February 21, 2016 symptoms were the result of an infection rather than the anti-NMDAR encephalitis, "the vaccinations received four days prior must nevertheless be considered the necessary and substantial cause." Exhibit 54 at 1. She opined that it is "plausible and logical" that the immune response to an infection, coinciding with the peak response to a vaccine, "could in combination provoke an aberrant immune response." Id. Dr. Marcus further opined that it was "unlikely" for a viral infection alone to trigger such a response.

Dr. Marcus criticized Dr. Lancaster for being "unable to give an exact mechanistic explanation" as to how an infection could trigger the onset of anti-NMDAR encephalitis. Exhibit 54 at 2. She stated that the relationship between "environmental triggers" and autoimmune encephalitis "is generally accepted as a reliable theory without requiring an accompanying explanation of the exact mechanisms involved," and "the lack of an exact mechanism should not prevent us from accepting the plausibility that immune response provoked by a vaccination would be similar to that in a postinfectious process." Id. Dr. Marcus further stated that, although there is a "lack of sufficient epidemiology assessing NMDARE following vaccination, epidemiological evidence does support a causal link between AE in general and the seasonal influenza vaccine." Id. She stated that the burden is "to identify a plausible biologic theory that the vaccine can cause AE and articulate the medical and scientific explanation in support of this." Id. at 3. Dr. Marcus maintained that the articles she cited and case reports supported the theory. Id.

In his second report, Dr. Lancaster reiterated his opinion that infection was the more likely cause of WCF's anti-NMDAR encephalitis. Exhibit C at 1. Several of the infectious symptoms would not have been caused by anti-NMDAR encephalitis, meaning there must have been a viral infection "replicating in the body for days before" and likely causing the disease. Id.

Dr. Lancaster also maintained that there is "no reliable, persuasive scientific evidence that vaccines trigger anti-NMDAR encephalitis." Exhibit C at 1. He stated that it was insufficient for Dr. Marcus to "just assert that molecular mimicry exists in general, and therefore we must consider this the likely disease mechanism in this case." Id. at 2. He clarified that his position was not requiring scientific certainty, but that he was rather applying a "more-likely-than-not" standard. As Dr. Marcus had not provided evidence of molecular mimicry between the vaccine

and disease, he did not find the theory was persuasive under that standard. Dr. Lancaster disputed the relevance and utility of the papers cited by Dr. Marcus. Id. at 2-3.

The submission of Dr. Lancaster's second report appeared to complete the disclosure of reports from experts. Ms. Faulkenberry affirmatively stated that an additional response was not required. Pet'r's Status Rep., filed Nov. 24, 2021.

Thus, the parties were directed to file briefs. Order, issued Jan. 21, 2022. This order alerted the parties that the case might be resolved on the papers. Ms. Faulkenberry filed her primary brief on July 6, 2022. With this submission, Ms. Faulkenberry submitted three affidavits, one from WCF's father, one from WCF's grandmother, and one from her. Exhibits 46-48. The affiants generally described WCF's health from February 21, 2016 (the date of the trip to Target) through his hospitalization in March 2016. The affiants also affirmed the accuracy of video testimony and incorporated that material. However, Ms. Faulkenberry did not submit any video testimony at this time.

In the context of Ms. Faulkenberry's initial set of materials, she submitted a third report from Dr. Marcus. Exhibit 54. She also submitted additional medical articles. Exhibits 49-53.

In compliance with the order scheduling briefs, the Secretary submitted his brief on September 6, 2022. The Secretary did not add another report from Dr. Lancaster. The Secretary noted that Ms. Faulkenberry had referenced but not actually submitted video testimony. Resp't's Br., filed Sep. 6, 2022, at 11.

Ms. Faulkenberry corrected her apparent oversight by submitting videos via a portable storage device. See CM/ECF 80. The videos, which are of poor quality, appear to show the three affiants in a setting resembling a deposition. An unidentified person, who does not appear on camera, asks questions and the person answers. A court reporter recorded the session. This submission appeared to ruffle feathers with the Secretary.

At the Secretary's request, a status conference was held. In the status conference, Mr. Ragsdale stated that a purpose of submitting the videos was to allow the special master to assess the witnesses' demeanor and credibility. He emphasized that because the order for briefs informed the parties that a hearing would not necessarily be held, Ms. Faulkenberry wanted to present her evidence. Mr. Ragsdale further contended that he may present evidence in any form. In Mr.

Ragsdale's view, he did not have to consult with opposing counsel about how he submits evidence.

Acting through Ms. Manoso, the Secretary argued that to the extent that Mr. Ragsdale conducted a deposition, the Secretary was entitled to notice. According to Ms. Manoso, if the Secretary had been notified about a deposition, then the Secretary would have participated in the deposition. The Secretary proposed striking the videos.

The videos were stricken because the quality of the videos was poor, not due to a lack of notice. Order, issued Oct. 14, 2022, citing Vaccine Rule 8(b). Ms. Faulkenberry was given an opportunity to submit new videos with transcripts. The Secretary also was given an opportunity to request a deposition. Id.

Ms. Faulkenberry submitted new videos and transcripts of the testimony created by a court reporter. Exhibits 60-62; see also CM/ECF 84. This testimony again mostly concerns whether WCF suffered from an infection when he was at Target.

After previously raising a kerfuffle about lack of notice and wanting to participate in any deposition, the Secretary declined to seek a deposition of the WCF's father, WCF's grandmother, and Ms. Faulkenberry. Resp't's Status Rep., filed Dec. 30, 2022. However, because Ms. Faulkenberry submitted evidence after the Secretary filed his brief, the Secretary submitted a revised brief on February 2, 2023.

Ms. Faulkenberry further argued her case. Pet'r's Reply, filed Mar. 27, 2023. With the submission of the reply, Ms. Faulkenberry's case is ready for adjudication.

Ms. Faulkenberry did not seek a hearing. See Pet'r's Br. The Secretary proposed that the case be resolved on the written record. Resp't's Revised Br. at 54. Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence

standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When a petitioner, like Ms. Faulkenberry, claims that a vaccine caused an injury not listed on the Vaccine Injury Table, such as anti-NMDAR encephalitis, the elements of a petitioner's case are well defined. A petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Ms. Faulkenberry's case is being resolved upon prong one exclusively. Thus, an examination of the remaining prongs is not required.

IV. Analysis

Three steps are required to evaluate Ms. Faulkenberry's assertion that a flu vaccine can cause anti-NMDAR encephalitis. The first is to determine the level of proof on this element. The second is to assess whether the evidence satisfies the standard. An additional aspect is to compare the outcome in Ms. Faulkenberry's case with the outcome in other cases evaluating Althen's first prong in the context of a flu vaccine allegedly causing anti-NMDAR encephalitis.

A. Burden of Proof for *Althen* Prong One

Ms. Faulkenberry recognizes that her burden of proof is preponderant evidence. Pet'r's Br. at 4, citing 42 U.S.C. § 300aa–13(a)(1)(A). But Ms. Faulkenberry argues that a medical theory proposing a causal connection between a vaccine and an injury needs to be only plausible. Id. at 5, 7 (citing cases); Pet'r's Reply at 1-3. Consistent with this position, Ms. Faulkenberry contends that the theory Dr. Marcus proposes is plausible. See, e.g. Pet'r's Br. at 12-15.

On the other hand, the Secretary argues that any medical theory must be persuasive and reliable. Resp't's Br. at 31-32. The Secretary, therefore, criticizes Ms. Faulkenberry for using the wrong standard. Id.

Plausibility requires a lower degree of evidence than probability. Cerrone v. Sec'y of Health & Hum. Servs., No. 17-1158V, 2023 WL 9185794, 168 Fed. Cl. 745, 753-54 (Fed. Cl. Nov. 6, 2023), appeal docketed, No. 24-1281 (Fed. Cir. Dec. 22, 2023); Jane Doe 93 v. Sec'y of Health & Hum. Servs., No. Redacted, 2011 WL 2326966, at *1 (Fed. Cl. Spec. Mstr. May 9, 2011); C.f. Amarin Pharm., Inc. v. Hikma Pharm., USA, Inc., 104 F.4th 1370, 1377 (Fed. Cir. 2024) (distinguishing between plausibility and probability in the context of evaluating a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure). An evidentiary scale might include markers for "what is possible," "what is plausible," "what is persuasive," "what is convincing," and "what is certain."

The question of whether the medical theory must be "probable" or "plausible" has arisen in multiple recent opinions. Generally, but not universally, judges from the Court of Federal Claims have held that the burden of proof for Althen prong one is persuasive evidence.[5] Examples of cases with particularly strong reasoning include: Trollinger v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 127, 137 (2023), Howard v. Sec'y of Health & Hum. Servs., No. 16-1592V, 2023 WL 4117370, at *4-5 (Fed. Cl. May 18, 2023) (discussing cases decided before Moberly), aff'd without opinion, No. 2023-1816, 2024 WL 2873301 (Fed. Cir. June 7, 2024), and Townsend v. Sec'y of Health & Hum. Servs., 170 Fed. Cl. 130 (Feb. 22, 2024), appeal docketed, No. 2024-1740 (Fed. Cir. Apr. 25, 2024).

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[5] These opinions from the Court of Federal Claims are not binding precedent. However, they remain a type of precedent from an appellate tribunal capable of persuading by their reasoning.

One prominent example of an opinion contrary to this trend is Hoffman v. Sec'y of Health & Hum. Servs., 172 Fed. Cl. 477 (2024).

As suggested in cases such as Trollinger, Howard, and Townsend, the Federal Circuit has stated "the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013).

A holding that Ms. Faulkenberry must present a persuasive theory, by itself, may justify a finding that Ms. Faulkenberry did not meet her burden of proof. As noted above, Ms. Faulkenberry consistently contended that her proof of a medical theory was plausible. See, e.g. Pet'r's Br. at 15 (Dr. Marcus opines that "these theoretical mechanisms [are] reliably plausible explanations"); see also Exhibit 54 at 3 (Dr. Marcus's third report stating that her undertaking is "to identify a plausible biologic theory that the vaccine can cause AE and articulate the medical and scientific explanation in support of this"). Proof at merely a plausible level is insufficient as a matter of law, as illustrated in Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351 (Fed. Cir. 2019). There, the petitioners' expert presented a theory that was "only 'plausible.'" Id. at 1360, quoting the special master's decision. The Federal Circuit held that the "Special Master erred in allowing a theory that was at best 'plausible' to satisfy the Petitioners' burden of proof." Id.

Given the outcome in Boatmon, which was a Federal Circuit's affirmance of a judgment denying compensation, it appears that a similar outcome should be reached here, a decision denying compensation. However, it is conceivable that the evidence surpasses the correct threshold even if Ms. Faulkenberry, herself, did not characterize her case that way. For this reason and to demonstrate that all evidence relevant to Althen prong one has been considered, the undersigned will next evaluate Ms. Faulkenberry's proposed theories.

B. Ms. Faulkenberry's Evidence

To meet her burden regarding Althen prong one, Ms. Faulkenberry presented various types of evidence. These include: (1) epidemiologic evidence, (2) case reports, and (3) the opinion of Dr. Marcus.

1. Epidemiologic Evidence

Ms. Faulkenberry asserts that she "has offered into evidence recently released epidemiology that persuasively demonstrates an increased risk of encephalitis following the flu vaccine." Pet'r's Br. at 15 n.10, citing Jedidi[6]; accord id. at 17, Pet'r's Reply at 6-7. This assertion is not persuasive for multiple reasons.

The journal Neurology published an abstract by Nour Jedidi and three other authors, including Nizar Souayah, on April 13, 2021. Jedidi at 1. Despite its publication more than three years ago, the Jedidi abstract has not been cited in any opinion by a special master. If the Jedidi article is potentially as powerful as described, this omission seems surprising.

The January 2, 2020 Instructions for experts stated: "the full version of [medical articles] must be filed [and] [a]bstracts are not permitted." Restricting the submission of abstracts reflects the lack of reliability of abstracts. Hazlehurst v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 473, 488 (2009) ("poster presentations are not subject to peer review and as a result do not receive the scrutiny of the scientific community that confers an element of reliability on published test results"), aff'd, 604 F.3d 1343 (Fed. Cir. 2010); Hennessey v. Sec'y of Health & Hum. Servs., No. 01-190V, 2009 WL 1709053, at *33 (Fed. Cl. Spec. Mstr. May 29, 2009) ("because I cannot determine from the abstract if this was a peer reviewed study, I have elected to place no weight upon it"), mot. for rev. denied, 91 Fed. Cl. 126 (2010).

In any event, the limited information available in the abstract shows a methodological flaw. The source of information for the Jedidi study was the Vaccine Adverse Event Reporting System database. The VAERS database is not a reliable source for conducting epidemiologic studies. H.L. v. Sec'y of Health & Hum. Servs., 715 Fed. App'x 990, 995-96 (Fed. Cir. 2017); Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 558 (2006); Ryman v. Sec'y of Health & Hum. Servs., 65 Fed. Cl. 35, 39-40 (2005); Tompkins v. Sec'y of Health & Hum. Servs., No. 10-261V, 2013 WL 3498652, at *26 n.66 (Fed. Cl. Spec. Mstr. June

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[6] Nour Jedidi et al., Encephalitis after Influenza Vaccination in the United States: A CDC/FDA Vaccine Adverse Event Reporting System Study, 1990–2018 (3052). 19 NEUROLOGY, supplement 15 (2021); filed as Exhibit 50.

21, 2013) (criticizing a study by Dr. Souayah, that used VAERS data and also "lacked an unvaccinated comparison population, rendering this study's conclusions poor evidence of causality"), mot. for rev. denied, 117 Fed. Cl. 713 (2014).

For these reasons, the Jedidi abstract provides little, if any, support for the proposition that the flu vaccine causes encephalitis.

2. Case Reports

In addition to advancing the Jedidi abstract, Ms. Faulkenberry puts forward four case reports: Cartisano, Hoffman, Endres, and Ussel. Pet'r's Br. at 17-18; see also Pet'r's Reply at 6-7. However, case reports are not persuasive evidence regarding causation.

In the context of litigation, case reports often do not receive much consideration as evidence of causation. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

Thus, ample authority supports the proposition that case reports generally are not helpful in assessing causation. In accord with these authorities, the undersigned declines to afford the case reports much weight in determining whether the flu vaccine can cause anti-NMDAR encephalitis. Moreover, there are specific limitations about the case reports in this case.

The Cartisano case report is actually an abstract. See Cartisano[7]; see also Pet'r's Status Rep., filed April 9, 2024. As previously mentioned, abstracts carry less reliability than full articles.

[7] Teodora Cartisano and Jennifer Kicker, Anti-N-methyl-D-Aspartate Receptor Encephalitis in 7-Month Old Infant Following Influenza Vaccination (P5.136), 86 NEUROLOGY, supplement 16 (2016); filed as Exhibit 51.

Two other case reports involve vaccines other than the vaccines WCF received. See Endres[8] (case report about tetanus-diphtheria-acellular pertussis and polio vaccine); Hoffman[9] (case report about tetanus-diphtheria-acellular pertussis and polio vaccine). Another case report involves a disease other than anti-NMDAR encephalitis. Ussel[10] at 12 (noting testing for anti-NMDAR antibodies were negative). Thus, extrapolation would be required to draw conclusions from these examples. See Alsaadeh v. Sec'y of Health & Hum. Servs., No. 19-1097V, 2024 WL 694072, at *32-33 (Fed. Cl. Spec. Mstr. Jan. 23, 2024); Thompson v. Sec'y of Health & Hum. Servs., No. 18-1217, 2023 WL 9053982, at *15 (Fed. Cl. Spec. Mstr. Dec. 5, 2023).

For these reasons, the case reports are entitled to relatively little weight.

3. Theory or Theories Dr. Marcus Advances

a) Disclosure of Theories

With respect to disclosing an opinion as to how either the hepatitis A vaccine or flu vaccine can cause anti-NMDAR encephalitis, the reports of Dr. Marcus may not be (or may be) a model of clarity. The struggle seems to be that there is little basis for linking the hepatitis A vaccine or flu vaccine to anti-NMDAR encephalitis.

In Dr. Marcus's first report, she disclosed a list of theories: "There are multiple mechanisms by which autoimmunity in encephalitis can be induced, including host infection, occult neoplasm, and vaccine reaction, which have been reviewed in the medical literature." Exhibit 22 at 4 (footnote omitted). From this group, it appears that Dr. Marcus chose molecular mimicry: "In my opinion,

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[8] Dominique Endres, Psychiatric Presentation of Anti-NMDA Receptor Encephalitis, 10 FRONT. NEUROL. 1086 (2019); filed as Exhibit 52.

[9] Caroline Hofmann et al., Anti-NMDA receptor encephalitis after TdaP-IPV booster vaccination: cause or coincidence?, 258 J. NEUROL. 500 (2010); filed as Exhibit 30.

[10] Isabella Van Ussel et al., Encephalitis related to a H1N1 vaccination: case report and review of the literature, 124 CLIN. NEUROL. NEUROSURG. 8 (2014); filed as Exhibit 36.

molecular mimicry is a reliable and accepted theory within the medical community that persuasively explains how the vaccines received by WCF more probably than not could cause the onset of anti-NMDARE." Id. In support of this opinion, Dr. Marcus cited some studies and some case reports that are discussed in this decision.

After Dr. Lancaster criticized this opinion, Dr. Marcus defended it. At times, she appears to have taken on the role of a lawyer arguing over the burden of proof: "it is not necessary to present mechanistic evidence that is deemed convincing to the scientific community as that is beyond the scope of the issue." Exhibit 44 at 4. She continued to discuss medical literature including one article by C. Hammer and others, in which the authors concluded "that loss of blood brain barrier integrity could be a contributing risk factor" for the development of anti-NMDAR encephalitis. Id. at 4-5 (citing Hammer at 1148)[11]. Other than this mention, Dr. Marcus did not elaborate on a theory involving the blood brain barrier. Further, Dr. Marcus did not explain how a study about an influenza infection might breach the blood-brain barrier could extend to an influenza vaccination. Any such explanation would need, at a minimum, to address that influenza viruses replicate, and the flu vaccine does not. Instead, Dr. Marcus maintained that molecular mimicry is a "reliable" "theoretical framework." Id. at 5.

Dr. Marcus's final report was written and filed in the context of the order for briefs. She, again, listed different theories. Many (and perhaps most) "autoimmune conditions" "have theoretical, multifactorial, and incompletely described mechanisms. In cases of presumed postinfectious autoimmunity, proposed mechanisms include polyclonal lymphocyte activation, epitope spreading, molecular mimicry, and antigen complementarity." Exhibit 54 at 2. Dr. Marcus added: "Also widely accepted is the fact that these principles might be at play in an autoimmune condition despite the fact that we currently do not have a tested, exact mechanistic description in a specific condition. In our case, the lack of an exact mechanism should not prevent us from accepting the plausibility that [an] immune response provoked by a vaccination would be similar to that in a

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[11] C. Hammer et al., Neuropsychiatric disease relevance of circulating anti-NMDA receptor autoantibodies depends on blood-brain barrier integrity, 10 MOL. PSYCHIATRY 1143 (2014); filed as Exhibit 40.

postinfectious process." Id. In this statement, Dr. Marcus appears to concede that there is a "lack of an exact mechanism."

Ms. Faulkenberry's brief is consistent with Dr. Marcus's reports in that Ms. Faulkenberry lists different theories without really engaging with the theory in a meaningful way. "The reliable immunologic theories are explained and include blood brain [barrier] disruption, molecular mimicry and epitope spreading." Pet'r's Br. at 24. "Beyond the accepted theoretical neuroimmunology framework, the specific mechanisms by which an environmental immune provocation develops into AE [autoimmune encephalitis], including the subset of AE involved here are not generally known."

To a degree, Dr. Marcus and Ms. Faulkenberry have tended to focus upon molecular mimicry. This was the Secretary's understanding as well. Resp't's Revised Br. at 15 n.5. Multiple appellate cases have provided guidance on how special masters should assess molecular mimicry. These non-binding precedents are discussed as a preliminary matter. After this foundation, the evidence is further evaluated.

b) Appellate Cases regarding Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role of reviewing opinions.[12] In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd sub nom., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

[12] The briefs would have been improved if they had discussed any appellate cases about molecular mimicry.

In the next approximately four years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.[13] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master

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[13] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." *Dorland's* at 868.

erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

The Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal withdrawn, No. 2024-1214 (Fed. Cir. Mar. 25, 2024). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop Guillain-Barré syndrome (GBS). Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The Chief Special Master denied entitlement. Id. at 656.

The Court of Federal Claims denied a motion for review because the Chief Special Master did not commit any error in evaluating Ms. Dennington's prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." Id. at 653.

- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." Id.

- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.

- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

> In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general her molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

In accordance with precedents such as W.C., Caves, Tulio, Yalacki, and Dennington, the undersigned will look to see whether any evidence supports the theory that flu vaccine can cause anti-NMDAR encephalitis.

c) Evidence regarding Molecular Mimicry

Apart from case reports and one study of the VAERS database, which are discussed above, Dr. Marcus does not persuasively establish the reliability of the molecular mimicry theory in the context of anti-NMDAR encephalitis. Her reports are general, lacking any specific explanation for how the hepatitis A vaccine or the flu vaccine can lead to anti-NMDAR encephalitis. See Exhibit 22 at 3, Exhibit 44 at 3-5, Exhibit 54.

The Secretary pointed out the generalities of Dr. Marcus's opinion:

> Preliminarily, there is a foundational deficit to petitioner's molecular mimicry theory of causation. Here, WCF received two vaccinations on February 16, 2016, a Hep A vaccine and a flu vaccine. For purposes of a vaccine theory of causation based on molecular mimicry, it is not clear whether Dr. Marcus believes that the alleged mimic resides in the flu vaccine, Hep A vaccine, or some combination. . . . Additionally, Dr. Marcus uses a generalized term, "autoimmune encephalitis," so it is not apparent whether the

> percentages she cites apply to WCF's specific condition of anti-NMDAR encephalitis or other types of encephalitis.

Resp't's Br. at 24-25. This description is apt.

In reply, Ms. Faulkenberry acknowledged that the Secretary "contends that Petitioner's theory is too generalized to be a more likely than not explanation for how the flu and Hep A vaccines can cause anti-NMDAR encephalitis." Pet'r's Reply at 3. Ms. Faulkenberry's reply does not enhance her case by pointing to evidence that makes her theory more specific. Rather, Ms. Faulkenberry cites rulings from special masters and argues that more specific evidence is not required. Id. at 3-5. As discussed in section IV.B.3.b) above, the general trend from appellate tribunals is that more specifics are required to carry the burden regarding Althen prong one.

The reasoning in opinions such as Dennington is consistent with an opinion from Dr. Lancaster about the generality of Dr. Marcus's opinion:

> Dr. Marcus argues that "the medical community considers molecular mimicry, acting possibly in combination with other mechanisms, to be a reliable theory explaining vaccine-induced autoimmunity." Ex 44. P3. This statement conflates a very general biological fact, namely that molecular mimicry has been proven to occur in very rare cases for specific diseases with specific triggers, with the question of whether molecular mimicry actually occurs for this specific disease with this specific mimic. Dr. Marcus does not provide any reliable evidence that molecular mimicry occurs for the specific vaccine in question to cause anti-NMDAR encephalitis. It is entirely insufficient for Dr. Marcus to just assert that molecular mimicry exists in general, and therefore we must consider this the likely disease mechanism in this case. If we accept Dr. Marcus's reasoning, then we would have to conclude that any vaccination can cause every autoimmune disease simply because molecular mimicry has been shown with other stimuli and other diseases.

Exhibit C at 1-2.

In Dr. Lancaster's first report, he stated that: "The key phenomenon which absolutely must occur for anti-NMDAR encephalitis to develop is the creation of specific antibodies targeting a specific 3-dimensional epitope on the GluN1 receptor subunit. These antibodies recognize the receptor in its intact membrane conformation." Exhibit A at 4. Although using slightly different nomenclature, Dr. Marcus agreed that "In anti-NMDA receptor encephalitis, auto-antibodies are produced against the cell surface NRl subunit of the NMDA receptor." Exhibit 22 at 3. Yet, Dr. Marcus does not hypothesize any way that the hepatitis A vaccine and/or the flu vaccine leads to the creation of antibodies to the specific protein that causes anti-NMDAR encephalitis. See Pet'r's Br. at 13 ("How environmental triggers induce the formation of the pathological auto-antibodies involved in anti-NMDARE and the pathways by which those antibodies reach the cell antigens cannot be identified with specificity"). This leaves a gap in Dr. Marcus's opinion regarding molecular mimicry and deprives Dr. Marcus's opinion of sufficient evidentiary weight to be reliable. "[A] Special Master need not credit expert opinion testimony that is connected to the existing data or methodology 'only by the ipse dixit of the expert,' or where 'there is simply too great an analytical gap between the data and the opinion proffered.'" Jarvis v. Sec'y of the Dep't of Health & Hum. Servs., 99 Fed. Cl. 47, 61 (2011), quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

In her discussion of molecular mimicry, Dr. Marcus cited an article by Wang. In Wang, a group of researchers identified an instance in which a two-year-old girl received her second dose of a Japanese encephalitis vaccine. She developed various problems and within approximately one month, was diagnosed with anti-NMDA receptor encephalitis. Wang at pdf 2-3[14].

The researchers wanted to investigate whether the Japanese encephalitis vaccine and other vaccines could be associated with anti-NMDAR encephalitis. To explore this possibility, the researchers analyzed the microRNA ("miRNA"). Id. at 3. "miRNAs are small RNA molecules approximately 22 nucleotides long that can upregulate or downregulate their target gene expression post-transcriptionally." Id. The researchers also conducted a "phylogenetic analysis."

[14] Hsiuying Wang, Anti-NMDA Receptor Encephalitis and Vaccination, 18 INT. J. MOL. SCI. 193 (2017); filed as Exhibit 41.

Id. "Phylogeny" refers to "the complete developmental history of a group of organisms." Dorland's at 1422. The researchers examined six vaccines of which the most relevant for this case is the H1N1 influenza vaccine. (The researchers did not analyze the hepatitis A vaccine.) Wang at pdf 3.

The authors recognized that one particular miRNA, let-7f, was downregulated in H1N1 infected cells. Id. at 3. Let-7f is also "downregulated in anti-NMDAR encephalitis compared with the negative controls." Id. at 4. How these findings related to each other, if they do relate to each other, was not discussed in the article. The article concludes that "it is worth investigating the association between JE vaccination and anti-NMDA receptor encephalitis." Wang at pdf 8.

Dr. Marcus did little to explain either the methodology or the results. See Exhibit 22 at 3. Something more from Dr. Marcus could have enhanced the value of her opinion. In contrast, Dr. Lancaster explained that "The levels of various miRNA change naturally to help regulate the levels of various proteins throughout life, and can change under many disease conditions including cancer, infections, etc." Exhibit C at 3. Dr. Marcus did not propose that the Wang group's use of a "phylogenetic analysis" could serve as a proxy for a showing of some homology. See Exhibit 54 at 3.

Dr. Marcus also cited the Hammer article in her discussion of molecular mimicry. She wrote: "a study of almost 3,000 patients tested for anti-NMDAR antibodies found [a] higher prevalence of anti-NMDAR antibodies in patients with anti-influenza A IgG." Exhibit 22 at 3. However, Dr. Lancaster questioned the value of this article, as "This paper did not study patients with antiNMDAR encephalitis." Exhibit C at 4. Dr. Lancaster's criticism seems well-founded. The lack of rebuttal from Dr. Marcus (see Exhibit 54) diminishes the value of the Hammer article.

d) Other Theories

As noted above, Dr. Marcus at least mentioned theories other than molecular mimicry. For example, she listed "host infection, occult neoplasm," "polyclonal lymphocyte activation, epitope spreading, . . . and antigen complementarity." Exhibit 22 at 4, Exhibit 54 at 2. None of these ideas are developed sufficiently enough for them to be persuasive. See Baron v. Sec'y of Health & Human Servs., No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019) (petitioners "need to propose something more than taking a vague 'kitchen sink'

approach and listing eleven mechanisms that have been previously submitted in the Program for claims of vaccine-caused injury with various degrees of success. Petitioners have listed many possibilities but have not identified a sound and reliable explanation that can be applied to the vaccines and injury in this case"). Likewise, Ms. Faulkenberry's brief barely mentions theories other than molecular mimicry. As such, any reliance on theories other than molecular mimicry is not persuasive.

4. Summary regarding Ms. Faulkenberry's Evidence

Ms. Faulkenberry's evidence regarding how the hepatitis A vaccine and/or the flu vaccine can cause anti-NMDAR encephalitis falls short. The study she identifies as an epidemiologic study (Jedidi) has not been shown to be reliable. The case reports are also problematic as discussed above.

Perhaps due to a lack of supporting articles, Dr. Marcus struggled to present a theory to explain how the vaccinations can cause anti-NMDAR encephalitis. Although literature is not required, Althen, 418 F.3d 1274, "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012). The theory that Dr. Marcus proposed as being the most likely, molecular mimicry, is not persuasive in this context.

For these reasons, Ms. Faulkenberry has not met her burden of proof regarding Althen prong one.

C. Other Cases from the Vaccine Program

The foregoing analysis is based upon the evidence and the parties' arguments about the evidence. See 42 U.S.C. § 300aa–13(a)(1) (directing a special master to consider "the record as a whole"). Another point meriting consideration is how other judicial officers have addressed similar points, even though those resolutions are not binding. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358-59 (Fed. Cir. 2019). Decisions from special masters do not bind other special masters because, in part, different special masters can weigh even similar evidentiary records differently. Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000).

The parties were encouraged to identify relevant cases involving a reasoned outcome. Order for Briefs, issued July 18, 2022, at 6. Ms. Faulkenberry cited

Agarwal v. Sec'y of Health & Hum. Servs., No. 16-191V, 2020 WL 5651683 (Fed. Cl. Spec. Mstr. Aug. 31, 2020) and Al-Uffi v. Sec'y of Health & Hum. Servs., No. 13-956V, 2017 WL 1713113 (Fed. Cl. Spec. Mstr. Feb. 22, 2017). Pet'r's Br. at 10-11, 31 n.24; Pet'r's Reply at 4-5.

In Agarwal, the petitioners claimed a tetanus vaccine caused their child to suffer autoimmune limbic encephalitis. 2020 WL 5651683, at *1. (Autoimmune limbic encephalitis is not exactly the same as anti-NMDAR encephalitis, which is the condition at issue in Ms. Faulkenberry's case.) The special master credited petitioners' proof on prong one because, in part, portions of the tetanus vaccine were homologous with nerve tissue. Id. at *25. Ms. Faulkenberry did not present this type of evidence.

In Al-Uffi, the petitioner alleged the human papillomavirus vaccine caused her son to suffer anti-NMDA receptor encephalitis, which is abbreviated in Al-Uffi as "ARE." 2017 WL 1713113, at * 1. Petitioner prevailed on prong one because her "not particularly robust" evidence concerning molecular mimicry met the "relatively lenient preponderance standard that is applied in Program cases." Id. at *21. However, after Al-Uffi, non-binding but still persuasive precedents from the Court of Federal Claims have invigorated the standards of proof regarding molecular mimicry. See, e.g., Dennington, Morgan, Yalacki. Thus, Al-Uffi carries relatively little precedential force.

By way of contrast, the Secretary cited Baron v. Sec'y of Health & Hum. Servs., No. 14-341V, 2019 WL 2273484 (Fed. Cl. Spec. Mstr. Mar. 18, 2019). Resp't's Revised Br. at 34. There, the petitioners alleged that the hepatitis A and/or the flu vaccine caused their child to suffer from anti-NMDAR encephalitis. Id. at *1. In defending against this claim, the Secretary retained Dr. Lancaster, who has also opined in Ms. Faulkenberry's case. See id. at *4. The special master found that the Barons had not met their burden of proof regarding Althen prong one because, in part, their expert could not link either the hepatitis A vaccine or the flu vaccine to the "very specific antibody" required in anti-NMDAR encephalitis. Id. at *17. This same flaw is present in Dr. Marcus's opinion.

The focus on the specific antibody is also present in a case another special master decided. L.R. by and through Baxter v. Sec'y of Health & Hum. Servs., No. 16-922V, 2024 WL 1912575, at *21 (Fed. Cl. Spec. Mstr. Mar. 28, 2024). The special master rejected molecular mimicry as a theory to explain how multiple vaccines might cause anti-NMDAR encephalitis. This conclusion is consistent with the result reached here in Ms. Faulkenberry's case.

D. Synopsis regarding Prong One

To meet her burden regarding Althen prong one, Ms. Faulkenberry has presented a variety of ideas arguing that it is biologically plausible for the hepatitis A vaccine and/or the flu vaccine to cause anti-NMDAR encephalitis. However, as explained in section IV.A, "biologic plausibility" is not the evidentiary standard. Under the correct evidentiary standard, Ms. Faulkenberry's evidence fails to measure up. There is little reliable support for claiming that the hepatitis A vaccine and/or flu vaccine can cause anti-NMDAR encephalitis. Any such theory would need to encompass the known etiology for the condition, which involves a specific subunit of the receptor.

V. Comments on Remaining *Althen* Prongs

When petitioners fail to establish one Althen prong, additional analysis is not required. Ms. Faulkenberry's case is resolved solely on the basis of Althen prong one.

A resolution on the basis of prong one obviates the need to consider some specific questions about what happened to WCF. For example, the parties dispute whether WCF suffered from any infection when he was sick in Target on February 21, 2016. See Pet'r's Br. at 3 and 36 and Resp't's Br. at 3, 12. If preponderant evidence established an infection, then this infection, in turn, could explain why WCF developed anti-NMDAR encephalitis. See Resp't's Br. at 36-37, citing Dr. Lancaster's reports. Similarly, a dispute as to when WCF began to manifest symptoms of anti-NMDAR encephalitis prevents an easy resolution of Althen prong three. See Resp't's Br. at 46 (arguing that WCF's anti-NMDAR encephalitis was manifested before the vaccination). Any resolution of Althen prongs two and three would be entirely academic and unnecessary to decide this case.

VI. Conclusion

Ms. Faulkenberry merits sympathy as her child has suffered. But she has not presented persuasive evidence that the hepatitis A vaccine and/or flu vaccine was the cause of WCF's anti-NMDAR encephalitis. Therefore, Ms. Faulkenberry is not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for

review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master